

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 07-4676 (JNE/AJB)

UNITED STATES OF AMERICA,)
ex rel. David Ketrosier, Gary Latz,)
Robert Smith and William Kennedy,)

Plaintiffs,)

v.)

MAYO CLINIC; MAYO)
COLLABORATIVE SERVICES, INC.;)
MAYO CLINIC-SAINT MARY'S)
HOSPITAL; MAYO CLINIC-)
METHODIST HOSPITAL,)

Defendants.)

**COMPLAINT OF THE
UNITED STATES IN
PARTIAL INTERVENTION**

The United States of America ("United States" or "the Government"), for its Complaint in Partial Intervention on Relators' First Amended Complaint, states and alleges as follows:

NATURE OF ACTION

1. The United States brings this action under the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), and common law against Defendants Mayo Clinic; Mayo Collaborative Services, Inc.; Mayo Clinic–St. Mary's Hospital; and Mayo Clinic–Methodist Hospital (collectively "Mayo" or "Defendants"), for falsely submitting claims for payment to the United States for surgical pathology services Mayo never performed.

2. This action pertains to conduct arising from Mayo's surgical pathology laboratories in Rochester, Minnesota. In these laboratories, pathologists use various techniques to examine human tissue removed from patients during surgery to help diagnose disease and guide in the overall care of those patients.

3. Mayo surgical pathologists often microscopically examine patient tissue. To do so, the tissue is prepared for examination in what are commonly referred to as "frozen slides," which are rapidly prepared to permit pathologists to analyze tissue during surgery, and/or "permanent slides," which take longer to prepare and are generally not available for review until the next day.

4. Mayo knowingly submitted or caused to be submitted false claims for payment to the United States, including Medicare, Medicaid, the Federal Employees Health Benefits Program ("FEHB"), TRICARE, and other government health care programs ("the Government Payers"), for permanent slides it never made and permanent slide examinations it never did.

5. In 2007, Mayo's Chair of its Division of Anatomic Pathology acknowledged that Mayo was billing for "a microscopic examination that doesn't exist," and "that someone could notify CMMS- [the Centers for Medicare & Medicaid Services] and there would be some serious issues." The Chair also acknowledged that the billing "has been going on for years," and that his predecessor "knew this occurred."

6. Each claim for payment Mayo submitted to the Government Payers for non-existent permanent slide services was false.

7. Based on Mayo's false claims for payment for surgical pathology services it did not perform, the Government Payers paid Mayo substantial sums of money to which Mayo was not entitled.

8. The United States, therefore, seeks judgment against the Defendants, jointly and severally, for its resulting damages, trebled under the FCA, plus civil penalties under the FCA, and such other and further relief as may be just and proper.

JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1345.

10. The Court has personal jurisdiction over the Defendants because they are incorporated in Minnesota and under 31 U.S.C. § 3732(a).

11. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because the Defendants reside and transact business in this District, as well as committed acts within this District that violated 31 U.S.C. § 3729.

PARTIES

A. Plaintiffs

12. The United States brings this action on behalf of its agency, the Department of Health and Human Services ("HHS"), and on behalf of the other Government Payers.

13. Relator David Ketroser ("Ketroser") is licensed to practice both medicine and law in the State of Minnesota. Ketroser currently resides in the District of Minnesota.

14. Relator Gary Latz (“Latz”) holds a durable power of attorney over the affairs of Betty L. Latz. Betty L. Latz is the widow of Leon Latz, a former Mayo Clinic patient. Latz resides in Addison, Texas.

15. Relator Robert Smith (“Smith”) is the widower of Dolores Smith, a former Mayo Clinic patient. Smith resides in the District of Minnesota.

16. Relator William Kennedy (“Kennedy”) is a former patient of the Mayo Clinic. Kennedy resides in the District of Minnesota.

B. Defendants

17. Defendant Mayo Clinic is a Minnesota non-profit corporation based in Rochester, Minnesota, with a principal place of business at 200 1st Street SW, Rochester, MN 55905. Mayo Clinic is part of the Mayo enterprise, which is comprised of a medical practice, hospital facilities, laboratories, and a medical school in Rochester, Minnesota, and a number of clinics and hospitals in other states. Mayo Clinic is also known as Mayo Foundation.

18. Defendant Mayo Collaborative Services, Inc. is a private Minnesota corporation based in Rochester, Minnesota with a principal place of business at 200 1st Street SW, Rochester, MN 55905. Mayo Collaborative Services, Inc. is also known as Mayo Medical Laboratories.

19. Defendant Mayo Clinic-Methodist Hospital is a Minnesota non-profit corporation based in Rochester, Minnesota with a principal place of business at 201 W. Center Street, Rochester, MN 55902. Mayo Clinic-Methodist Hospital is also known as Rochester Methodist Hospital.

20. Defendant Mayo Clinic-Saint Mary's Hospital is a Minnesota non-profit corporation based in Rochester, Minnesota, with a principal place of business at 1216 2nd Street SW, Rochester, MN 55902. Mayo Clinic-Saint Mary's Hospital is also known as Saint Mary's Hospital of Rochester, Minnesota.

THE FALSE CLAIMS ACT

21. The False Claims Act provides, in part, that:

Any person who-- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval; [or] (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; . . .

is liable to the United States Government for a civil penalty of not less than...[\$5,500 and not more than \$11,000], plus 3 times the amount of damages which the Government sustains because of the act of that person....

For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information-- (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(a), (b) (pre-2009 amendments); 28 C.F.R. § 85.3. *See also* 31 U.S.C. § 3729(a)(1)(A), (B), (b) (current version of False Claims Act).

THE GOVERNMENT PAYERS

22. Mayo submitted or caused to be submitted false surgical pathology claims to numerous United States agencies and health care programs and their contractors,

intermediaries, administrators, carriers, and/or grantees, including, but not limited to, those described below.

23. Mayo submitted false surgical pathology claims to Medicare, the federal health insurance program for the elderly and those with certain disabilities or chronic medical conditions. *See* 42 U.S.C. §§ 1395 *et seq.*

24. Medicare claims comprise the highest percentage of Mayo's surgical pathology claims to the Government Payers.

25. Mayo also submitted false surgical pathology claims to the Medicaid program.

26. Medicaid is jointly financed by the United States and the states. The Centers for Medicare & Medicaid Services ("CMS") administers Medicaid on the federal level. *See* 42 U.S.C. §§ 1396 *et seq.*

27. Claims made by Mayo to a state Medicaid program, when paid, cause the state Medicaid program to submit claims to CMS for the federal share of the total Medicaid expenditure.

28. The federal share of Medicaid expenditures is significant. For example, the federal share of Minnesota Medicaid expenditures is approximately 50%. The precise federal share changes annually.

29. Mayo also submitted or caused to be submitted false surgical pathology claims to the Federal Employees Health Benefits Program ("FEHB"), the federal health insurance program for federal employees and retirees. FEHB is administered by the

United States Office of Personnel Management, and funded by the United States. *See* 5 U.S.C. § 8901 *et seq.*

30. Mayo also submitted or caused to be submitted false surgical pathology claims to TRICARE, a federal health insurance program for uniformed service members, certain former uniformed service members, and their families. TRICARE is administered by the United States Department of Defense and funded by the United States. *See* 10 U.S.C. § 1071 *et seq.*

MAYO'S SURGICAL PATHOLOGY PRACTICE

31. Surgical pathology involves the examination of tissue specimens removed from patients to diagnose disease and guide in the care of those patients.

32. Mayo surgical pathologists often microscopically examine tissue. To do so, the tissue is thinly sliced into specimens, which are then prepared, stained, and placed on a slide for microscopic examination.

33. Mayo can create at least two types of slides in this process, which it refers to as “frozen” and “permanent.”

34. At all times relevant to these allegations, Mayo created frozen slides for most patients who received surgical pathology services at Mayo's Rochester facilities.

35. Mayo prepared the frozen slides by freezing a portion of the patient's tissue and slicing a thin frozen specimen for staining with a water-based toluidine blue (“T-Blue”) solution before placing it on a slide. The resulting slide was then examined, and a diagnosis was made based on the pathologist's frozen slide review.

36. Mayo generally created these frozen slides and reviewed them while the patient was in the operating room.

37. In some cases, Mayo also prepared permanent slides for its surgical patients. Mayo generally did so by retaining a portion of the patient's tissue that was not used for the frozen slide, and staining it using a hematoxylin and eosin ("H&E") or other permanent stain solution. After staining the tissue, Mayo placed it in paraffin to allow it to set overnight.

38. In such cases, Mayo asserts that the following day its personnel cut the tissue into specimens that were placed on one or more permanent slides for review under a microscope.

39. In some cases, however, Mayo prepared one or more frozen slides for a specimen, but did not prepare or examine any permanent slide for that specimen.

40. Mayo characterized these as "Block Only" specimens. This term refers to the fact that Mayo placed patient tissue in paraffin blocks, but never created or examined a permanent slide from such tissue.

41. The allegations in this Complaint address Mayo's practice of billing the Government Payers for permanent slides it never made and permanent slide examinations it never did.

SURGICAL PATHOLOGY BILLING BACKGROUND

42. Mayo submitted or caused to be submitted claims for payment for surgical pathology services to the Government Payers, including through their contractors, administrators, carriers, intermediaries, and/or grantees.

43. Mayo signed provider agreements and enrollment forms required by the Government Payers in which it stated it would abide by the laws, rules, and regulations governing the government health care programs, including the submission of truthful and accurate claims for payment.

44. For example, in its provider agreement with Medicare, Mayo stated that it understood that “payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with ... [applicable] laws, regulations and program instructions....”

45. In submitting claims for payment to the Government Payers for surgical pathology services, Mayo was obligated to submit true and accurate claims for services that Mayo in fact provided or performed.

A. CPT Codes

46. The American Medical Association (“AMA”) assigns and publishes numeric codes, representing a systematic listing of health care procedures and services, known as Current Procedural Terminology (“CPT”) codes. The AMA publishes these CPT codes annually in the CPT Manual.

47. As required by law, Mayo used the CPT codes to submit claims for payment for surgical pathology services to the Government Payers.

48. Mayo agreed to familiarize itself with, and abide by, Government Payer claims requirements, including, but not limited to, accurate use of CPT codes.

49. Mayo’s CPT-based claims included claims for surgical pathology services in the hospital inpatient, hospital outpatient, and clinic settings.

50. CPT codes are grouped into sections, including one entitled “Pathology and Laboratory.” This section has a series of CPT Codes beginning at 88300 for surgical pathology services.

51. In submitting claims for payment to the Government Payers, providers also sometimes use modifier codes, which are added to the end of a CPT code. Among other things, these modifier codes allow providers to bill separately for certain components of a CPT code.

52. Two such modifiers are particularly relevant to the surgical pathology claims at issue: the “26” modifier, which a provider can use to separately bill for the “professional” (*i.e.* physician-rendered) component of a service; and the “TC” modifier, which a provider can use to separately bill for the “technical” component of a service.

B. Claims

53. Mayo submitted or caused to be submitted surgical pathology claims for payment to the Government Payers, including to Medicare on CMS-1500 claims forms or their electronic equivalent and on CMS-1450 (UB-04) claims forms or their electronic equivalent.

54. Mayo represented that its claims were true, accurate, and lawful.

55. The Government Payers paid Mayo’s CPT-based surgical pathology claims based on those claims. The Government Payers would not have paid the claims had they known the claims were not true, accurate, and lawful.

MAYO'S BILLING FOR FROZEN AND PERMANENT SLIDES

56. Mayo billed the Government Payers for frozen slides using the 88331 and 88332 CPT codes.

57. Mayo billed the Government Payers for permanent slides using the following CPT codes: 88302, 88304, 88305, 88307 and 88309 (the "Permanent Slide Codes").

58. Mayo often used modifiers to submit separate claims for payment to the Government Payers for the professional and technical components of a Permanent Slide Code.

59. The CPT Manual requires that, for each Permanent Slide Code, a provider must prepare a slide containing the tissue, microscopically examine the tissue on the permanent slide, and report the results of such examination.

MAYO'S FALSE CLAIMS

60. During the relevant time period, Mayo knew that some of its surgical pathology specimens were "Block Only" specimens, meaning that Mayo did not create or examine a permanent slide for such specimens.

61. In 2008, the College of American Pathologists conducted an accreditation review of Mayo's practices and concluded that "for a substantial portion of the tissue blocks, a pathologist never reviews a permanent slide."

62. Mayo knew that it was not permitted to submit a claim for payment under a Permanent Slide Code if it did not make or examine a permanent slide for a specimen.

63. Mayo routinely submitted or caused to be submitted claims for payment to the Government Payers for at least one CPT code in the 88302-88309 Permanent Slide Code range for the “Block Only” specimens.

64. Mayo’s documents reflect that it submitted such claims “for years.”

65. The Government Payers paid Mayo for permanent slides it did not make or examine due to Mayo’s false claims.

66. Mayo contends that in September 2007, it stopped submitting claims for payment to the Government Payers for permanent slides it did not make or examine.

67. In November 2008, after the United States issued Mayo a subpoena seeking information concerning Mayo’s laboratory and billing practices relating to microscopic tissue examinations, Mayo refunded certain inadequate amounts to the Government Payers. Mayo’s refund did not fully and adequately pay the full measure of damages to which the United States is entitled in this action, nor did the United States approve or accept the refund in satisfaction of its claims herein.

MAYO’S KNOWLEDGE OF ITS FALSE CLAIMS

68. Mayo knew that it was routinely making claims for payment to the Government Payers under a Permanent Slide Code for the “Block Only” specimens.

69. At a minimum, Mayo acted in deliberate ignorance of the truth or falsity of its claims for payment to the Government Payers under a Permanent Slide Code for the “Block Only” specimens, or recklessly disregarded whether such claims were true and accurate.

70. Mayo knew that many of its surgical pathology specimens were “Block Only.” In 2004, Mayo created a list of tissue types that it regularly processed as “Block Only.” The list contains more than 30 tissue types.

71. In many cases, Mayo’s surgical pathology documentation reflects that Mayo assigned Permanent Slide Codes to associated tissue specimens that were “Block Only.”

72. Although Mayo knew that it did not make or examine permanent slides for many of its specimens, it nevertheless submitted claims for payment to the Government Payers for permanent slides it did not make or examine.

73. Mayo’s surgical pathologists are responsible for verifying the accuracy of claims for their services submitted for payment to the Government Payers.

74. Mayo’s policies and procedures, as well as applicable laws, regulations, and rules governing health care claims submissions to the Government Payers, required Mayo’s surgical pathologists to verify the accuracy of claims for their services submitted to the Government Payers.

75. In 2005, Mayo hired CPT coding specialists to review surgical pathology laboratory claims after the services were rendered, and before the claims were submitted to the Government Payers.

76. Thereafter, through at least September 2007, Mayo continued to submit or cause to be submitted claims to the Government Payers for permanent slides it did not make or examine.

77. In September 2007, Mayo's Chair of its Division of Anatomic Pathology acknowledged that Mayo was billing for "a microscopic examination that doesn't exist." He further acknowledged that "someone could notify CMMS [CMS]- and there would be some serious issues." He further acknowledged that the billing "has been going on for years," and that his predecessor "knew this occurred."

REPRESENTATIVE EXAMPLES OF MAYO'S FALSE CLAIMS

78. The following are representative examples of Mayo's false claims.

79. In 2002, Mayo billed Medicare for an 88304 Permanent Slide Code for beneficiary M.G. for date of service April 22, 2002, corresponding with an internal Mayo case number CR02-3395. Mayo, however, did not prepare or examine any permanent slides for M.G. in connection with this date of service.

80. In 2003, Mayo billed Medicare for an 88304 Permanent Slide Code for beneficiary O.E. for date of service August 12, 2003, corresponding with an internal Mayo case number CR03-6681. Mayo, however, did not prepare or examine any permanent slides for O.E. in connection with this date of service.

81. In 2006, Mayo billed Medicare for an 88304 Permanent Slide Code for beneficiary H.W. for date of service February 14, 2006, corresponding with an internal Mayo case number CR06-1283. Mayo, however, did not prepare or examine any permanent slides for H.W. in connection with this date of service.

82. In 2006, Mayo billed Medicare for an 88304 Permanent Slide Code for beneficiary I.R. for date of service February 22, 2006, corresponding with an internal

Mayo case number CR06-1473. Mayo, however, did not prepare or examine any permanent slides for I.R. in connection with this date of service.

83. In 2006, Mayo billed Medicare for an 88304 Permanent Slide Code for beneficiary P.M. for date of service September 7, 2006, corresponding with an internal Mayo case number MR06-8363. Mayo, however, did not prepare or examine any permanent slides for P.M. in connection with this date of service.

84. In 2007, Mayo billed Medicare for an 88304 Permanent Slide Code for patient R.S. for date of service July 18, 2007, corresponding with an internal Mayo case number CR07-5736. Mayo, however, did not prepare or examine any permanent slides for R.S. in connection with this date of service.

85. Medicare paid Mayo for its false claims in the preceding six paragraphs.

CLAIMS FOR RELIEF

COUNT ONE - FALSE CLAIMS ACT

86. Plaintiff incorporates by reference paragraphs 1 through 85 of this Complaint.

87. By the acts described above, Mayo knowingly presented, or caused to be presented to an officer, employee, agent or contractor of the United States, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) (pre-2009 amendments) and 31 U.S.C. § 3729(a)(1)(A) (current version of False Claims Act).

88. By the acts described above, Mayo knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or

approved by the United States, or material to a false or fraudulent claim, in violation of 31 U.S.C. § 3729(a)(2) (pre-2009 amendments) and 31 U.S.C. § 3729(a)(1)(B) (current version of False Claims Act).

89. The United States, as a result of Mayo's false or fraudulent claims, paid such claims, thereby resulting in damage to the United States in an amount to be determined at trial.

COUNT TWO - UNJUST ENRICHMENT

90. Plaintiff incorporates by reference paragraphs 1 through 85 of this Complaint.

91. The United States paid Mayo for claims that Mayo submitted or caused to be submitted for services that it did not perform and were not properly payable.

92. Mayo, by its receipt of the payments from the United States for services not actually performed, was unjustly enriched to the detriment of the United States in an amount to be determined at trial.

COUNT THREE - PAYMENT UNDER MISTAKE OF FACT

93. Plaintiff incorporates by reference paragraphs 1 through 85 of this Complaint.

94. Mayo made false representations and records concerning surgical pathology services it did not perform that were material to the United States' determination to pay Mayo for those services.

95. The United States relied on Mayo's false representations and records, and erroneously believed that Mayo was entitled to payment, without knowing that Mayo had not performed the services for which it was paid.

96. The United States would not have paid Mayo for services that Mayo did not perform if the United States had known the true facts.

97. The United States, relying on Mayo's representations and records regarding the performance, necessity, and appropriate billing for the surgical pathology services, paid such claims to Mayo, thereby resulting in damages to the United States in an amount to be determined at trial.

WHEREFORE, the United States demands that judgment be entered in its favor and against Defendants, jointly and severally, as follows:

- a. On COUNT ONE in the amount of triple the United States' damages plus penalties as allowed by law;
- b. On COUNTS TWO and THREE in the amount of the United States' damages;
- c. On ALL COUNTS for prejudgment interest, the costs of this action, and such other and further relief to which the United States may be entitled.

Dated: December 20, 2010

Respectfully submitted,

B. TODD JONES
United States Attorney

s/ Chad A. Blumenfield

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